

### III. Remarks

Claims 32-82 are pending and have been maintained in their previous form.

Independent claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Ammann et al. in view of Melet. However, this rejection is not warranted for the following reasons.

As the PTO recognizes in MPEP §2142:

*The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.*

Claim 32 recites the unique combination of conveying means for moving along a closed path and for receiving at least one vessel; a dispenser for dispensing a reagent, or the like, into the vessel as it moves along the path; at least one nozzle adapted for insertion into the vessel; means for effecting relative vertical movement between the nozzle and the vessel in order to insert the nozzle into the vessel; and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other than a precipitate, from the vessel and into the nozzle.

The examiner clearly cannot establish a *prima facie* case of obviousness in connection with claim 32 since 35 U.S.C. §103(a) provides that:

*[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains ... (emphasis added)*

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, Ammann et al., and Melet, alone, or in combination, do not teach the above features of claim 32 since neither reference teaches a mechanism for inclining a nozzle together with the vessel.

Regarding the means for inclining the receptacles of Melet, the following descriptions are found in the Melet specification in column 2, lines 21- 39 and column 4, lines 63-68:

*"...pierces the stopper to perform the sample removal then the transfer of all or part of the contents of the receptacle necessary for the analysis, it is established that the liquid to be analyzed is subjected to a dual agitation, due on the one hand to the rotation of the drum and, on the other hand, to the slope of the axis of each receptacle. This dual agitation, by rotation and tipping of the receptacle, favors homogenization of the sample to be analyzed without damage as a result of its fragility, which is particularly important in the case of blood samples and  
"Such a tipping movement of the sample before analysis, intentionally limited as a result of the low angle of slope of the receptacle relative to the axis 12 of the device, contributes to good homogenization of the product to*

*be analyzed without damage to its constitution and in particular without causing rupture of the cells in the case of analysis of blood."*

Also, in column 4, lines 42 to 48 of Melet, there is the following description:

*"During use of the device according to the invention in or with an automatic analyzer, the axis 12 of the drum 11 is not, as shown in FIGS. 1 to 2, vertical but horizontal, and the device rotates about this axis to present each of the receptacles 17 to the needle of the system responsible for removing the sample to be analyzed by perforating the stopper closing the receptacle 18."*

Thus, in Melet, inclination of receptacles against the axis of the drum (which is not vertical, but horizontal) is performed by rotating the drum to which the receptacles are mounted. However the needle responsible for removing the sample is not mounted on the drum, and a mechanism for inclining the needle together with the receptacles is not disclosed since the needle is distinct from the nozzle which receives the liquid.

Since the Examiner recognizes that Ammann, et al does not teach a mechanism for inclining a needle or nozzle with respect to a vertical axis and, based on the above, Melet does not cure this defect, it follows that the combination of Melet and Ammann et al. is insufficient to meet the limitations of claim 32.

Therefore, it is impossible to render the subject matter of claim 32 as a whole obvious based on any combination of the patents, and the above explicit terms of the statute cannot be met. As a result, the examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 32, and a rejection under 35 U.S.C. §103(a) is not applicable.

There is still another compelling, and mutually exclusive, reason why the Ammann et al., and Melet patents cannot be combined and applied to reject claim 32 under 35 U.S.C. §103(a).

The PTO also provides in MPEP §2142:

*[T]he examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. ...[I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.*

Here, Ammann et al., and Melet do not teach, or even suggest, the desirability of the combination since neither teaches or suggests providing conveying means for moving along a closed path and for receiving at least one vessel; a dispenser for dispensing a reagent, or the like, into the vessel as it moves along the path; at least one nozzle adapted for insertion into the vessel; means for effecting relative vertical movement between the nozzle and the vessel in

order to insert the nozzle into the vessel; and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other than a precipitate, from the vessel and into the nozzle.

Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 32.

In this context, the MPEP further provides at §2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (emphasis in original)*

There is still another compelling, and mutually exclusive, reason why the Ammann et al., and Melet patents cannot be combined and applied to reject claim 32 under 35 U.S.C. §103(a).

The courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In the present case it is clear that the examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 32.

In particular, in the present case the means for inclining the receptacles of Melet are used for dual agitation so as to favor homogenization of the sample to be analyzed. Therefore, there is no motivation to combine Ammann et al. which has a device for agitating containers already (see Abstract etc.), with Melet whose subject matter of the invention relates to homogenization of the sample to be analyzed and is diametrically opposite to that of the present invention which relates to extraction of a liquid other than precipitate, in order to minimize agitation of container, but extract liquid other than a precipitate from vessel and into the nozzle.

In contrast thereto, with the present invention, means for effecting relative vertical movement between the nozzle and vessel in order to insert the nozzle into the vessel, and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other than a precipitate, from the vessel and into the nozzle are mounted in an automatic separator/extractor. Namely, with the present invention, liquid other than a precipitate, can efficiently and easily be extracted by use of the mechanism for inclining both said nozzle and vessel with respect to said vertical axis (and not inclining only the vessel with respect to horizontal axis as Melet) so as to change the angle between the axis of the vessel and nozzle and the vertical axis in accordance with the amount or level of remaining liquid in the vessel without influencing the precipitate as is shown on page 8, lines 20 to 23, of the original specification. Hence, the apparatus of claim 32 of the present invention not only is distinct from

the Melet and Ammann et al. in that a mechanism for inclining the nozzle and vessel with respect to a vertical axis is mounted, but also has the aforementioned remarkable advantages. Consequently, the present invention cannot be easily made on the basis of Ammann et al. and Melet and is not obvious to a person of ordinary skill in the art.

Therefore, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 32, and the rejection under 35 U.S.C. §103(a) is not applicable.

Therefore, the rejection of independent claim 32 based on the combination of Ammann et al. and Melet under 35 USC § 103 (a), is unwarranted and should be withdrawn.

Claim 63 recites the unique combination of a liquid extraction device; a microplate having a plurality of wells; a plurality of nozzles communicating with the liquid extraction device and insertable into the wells; a movement mechanism for effecting relative movement between the nozzles and the microplate to insert the nozzles into the wells of the microplate; and an incline mechanism for inclining the nozzle and microplate with respect to a vertical axis so that a liquid, other than a precipitate, is drawn in the nozzle or is discharged from an opening in the microplate.

Claim 63 was rejected as being unpatentable over Ammann et al. in view of Melet and Butz under 35 U.S.C. §103(a). However, this rejection is unwarranted for the following reasons.

The examiner clearly cannot establish a *prima facie* case of obviousness in connection with claim 63 since 35 U.S.C. §103(a) provides that:

*[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains ... (emphasis added)*

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, Ammann et al., and Melet, alone, or in combination, do not teach the above features of claim 63 since neither reference teaches an incline mechanism for inclining the nozzle and microplate with respect to a vertical axis so that a liquid, other than a precipitate, is drawn in the nozzle or is discharged from an opening in the microplate.

Regarding the means for inclining the receptacles of Melet, the following descriptions are found in the Melet specification in column 2, lines 21- 39 and column 4, lines 63-68:

*"pierces the stopper to perform the sample removal then the transfer of all or part of the contents of the receptacle necessary for the analysis, it is established that the liquid to be analyzed is subjected to a dual agitation, due on the one hand to the rotation of the drum and, on the other hand, to the slope of the axis of each receptacle. This dual agitation, by rotation and tipping of the receptacle, favors homogenization of the sample to be*

*analyzed without damage as a result of its fragility, which is particularly important in the ease of blood samples and "Such a tipping movement of the sample before analysis, intentionally limited as a result of the low angle of slope of the receptacle relative to the axis 12 of the device, contributes to good homogenization of the product to be analyzed without damage to its constitution and in particular without causing rupture of the cells in the case of analysis of blood."*

Also, in column 4, lines 42 to 48 of Melet, there is the following description:

*"During use of the device according to the invention in or with an automatic analyzer, the axis 12 of the drum 11 is not, as shown in FIGS. 1 to 2, vertical but horizontal, and the device rotates about this axis to present each of the receptacles 17 to the needle of the system responsible for removing the sample to be analyzed by perforating the stopper closing the receptacle 18."*

Thus, in Melet, inclination of receptacles against the axis of the drum (which is not vertical, but horizontal) is performed by rotating the drum to which the receptacles are mounted. However the needle responsible for removing the sample is not mounted on the drum, and a mechanism for inclining the needle together with the receptacles is not disclosed since the needle is distinct from the nozzle which receives the liquid.

Butz was cited for an incidental teaching and does not cure the defects of Ammann et al. and Melet highlighted above.

Since the Examiner recognizes that Ammann, et al., does not teach a mechanism for inclining a needle or nozzle with respect to a vertical axis and, based on the above, Melet and Butz do not cure this defect, it follows that the combination of the three patents is insufficient to meet the limitations of claim 63.

Therefore, it is impossible to render the subject matter of claim 63 as a whole obvious based on any combination of the patents, and the above explicit terms of the statute cannot be met. As a result, the examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 63, and a rejection under 35 U.S.C. §103(a) is not applicable.

There is still another compelling, and mutually exclusive, reason why the Ammann et al., Melet, and Butz patents cannot be combined and applied to reject claim 63 under 35 U.S.C. §103(a).

The PTO also provides in MPEP §2142:

*[T]he examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. ...[I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.*

Here, Ammann et al., Melet, and Butz do not teach, or even suggest, the desirability of the combination since neither teaches or suggests providing conveying means for moving along a closed path and for receiving at least one vessel; a dispenser for dispensing a reagent, or the like, into the vessel as it moves along the path; at least one nozzle adapted for insertion into the vessel; means for effecting relative vertical movement between the nozzle and the vessel in order to insert the nozzle into the vessel; and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other than a precipitate, from the vessel and into the nozzle.

Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 63.

In this context, the MPEP further provides at §2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (emphasis in original)*

There is still another compelling, and mutually exclusive, reason why the Ammann et al., Melet, and Butz patents cannot be combined and applied to reject claim 63 under 35 U.S.C. §103(a).

The courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In the present case it is clear that the examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 63.

In particular, in the present case the means for inclining the receptacles of Melet are used for dual agitation so as to favor homogenization of the sample to be analyzed. Therefore, there is no motivation to combine Ammann et al. which has a device for agitating containers already (see Abstract etc.), with Melet whose subject matter of the invention relates to homogenization of the sample to be analyzed and is diametrically opposite to that of the present invention which relates to extraction of a liquid other than precipitate, in order to minimize agitation of the container, but extract liquid other than a precipitate from the vessel and into the nozzle.

In contrast thereto, with the present invention, means for effecting relative vertical movement between the nozzle and vessel in order to insert the nozzle into the vessel, and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other

than a precipitate, from the vessel and into the nozzle are mounted in an automatic separator/extractor. Namely, with the present invention, liquid other than a precipitate can efficiently and easily be extracted by use of the mechanism for inclining both said nozzle and vessel with respect to said vertical axis (and not inclining only the vessel with respect to the horizontal axis as Melet) so as to change the angle between the axis of the vessel and nozzle and the vertical axis in accordance with the amount or level of remaining liquid in the vessel without influencing the precipitate as is shown on page 8, lines 20 to 23, of the original specification. Hence, the apparatus of claim 63 not only is distinct from the Melet and Ammann et al. patents in that a mechanism for inclining the nozzle and vessel with respect to a vertical axis is mounted, but also has the aforementioned advantages. Consequently, the present invention cannot be easily made on the basis of Ammann et al., Melet, and Butz and is not obvious to a person of ordinary skill in the art.

Therefore, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 63, and the rejection under 35 U.S.C. §103(a) is not applicable.

Therefore, the rejection of independent claim 63 based on the combination of Ammann et al., Melet, and Butz under 35 USC § 103 (a), is unwarranted and should be withdrawn.

Independent claim 64 was rejected based on the combination of Ammann et al. and Melet under 35 USC § 103 (a). However, this rejection is unwarranted for the following reasons.

Claim 64 recites the unique combination of a conveying a vessel along a closed path; dispensing a reagent, or the like, into the vessel as it moves along the path; effecting relative vertical movement between the nozzle and the vessel to insert the nozzle into the vessel; and inclining the nozzle and vessel with respect to a vertical axis to extract liquid, other than a precipitate, from the vessel and into the nozzle.

The examiner clearly cannot establish a *prima facie* case of obviousness in connection with claim 64 since 35 U.S.C. §103(a) provides that:

*[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains ... (emphasis added)*

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, Ammann et al., and Melet, alone, or in combination, do not teach the above features of claim 64 since neither reference teaches an incline mechanism for inclining the nozzle and microplate with respect to a vertical axis so that a liquid, other than a precipitate, is drawn in the nozzle or is discharged from an opening in the microplate.

Regarding the means for inclining the receptacles of Melet, the following descriptions are found in the Melet specification in column 2, lines 21- 39 and column 4, lines 63-68:

*"pierces the stopper to perform the sample removal then the transfer of all or part of the contents of the receptacle necessary for the analysis, it is established that the liquid to be analyzed is subjected to a dual agitation, due on the one hand to the rotation of the drum and, on the other hand, to the slope of the axis of each receptacle. This dual agitation, by rotation and tipping of the receptacle, favors homogenization of the sample to be analyzed without damage as a result of its fragility, which is particularly important in the case of blood samples and*

*"Such a tipping movement of the sample before analysis, intentionally limited as a result of the low angle of slope of the receptacle relative to the axis 12 of the device, contributes to good homogenization of the product to be analyzed without damage to its constitution and in particular without causing rupture of the cells in the case of analysis of blood."*

Also, in column 4, lines 42 to 48 of Melet, there is the following description:

*"During use of the device according to the invention in or with an automatic analyzer, the axis 12 of the drum 11 is not, as shown in FIGS. 1 to 2, vertical but horizontal, and the device rotates about this axis to present each of the receptacles 17 to the needle of the system responsible for removing the sample to be analyzed by perforating the stopper closing the receptacle 18."*

Thus, in Melet, inclination of receptacles against the axis of the drum (which is not vertical, but horizontal) is performed by rotating the drum to which the receptacles are mounted. However the needle responsible for removing the sample is not mounted on the drum, and a mechanism for inclining the needle together with the receptacles is not disclosed since the needle is distinct from the nozzle which receives the liquid.

Since the Examiner recognizes that Ammann, et al., does not teach a mechanism for inclining a needle or nozzle with respect to a vertical axis and, based on the above, Melet does not cure this defect, it follows that the combination of Melet and Ammann et al. is insufficient to meet the limitations of claim 64.

Therefore, it is impossible to render the subject matter of claim 64 as a whole obvious based on any combination of the patents, and the above explicit terms of the statute cannot be met. As a result, the examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 64, and a rejection under 35 U.S.C. §103(a) is not applicable.

There is still another compelling, and mutually exclusive, reason why the Ammann et al., Melet, and Butz patents cannot be combined and applied to reject claim 64 under 35 U.S.C. §103(a).



The PTO also provides in MPEP §2142:

*[T]he examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. ...[I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.*

Here, neither Ammann et al., nor Melet teach, or even suggest, the desirability of the combination since neither teaches or suggests providing conveying means for moving along a closed path and for receiving at least one vessel; a dispenser for dispensing a reagent, or the like, into the vessel as it moves along the path; at least one nozzle adapted for insertion into the vessel; means for effecting relative vertical movement between the nozzle and the vessel in order to insert the nozzle into the vessel; and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other than a precipitate, from the vessel and into the nozzle.

Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 64.

In this context, the MPEP further provides at §2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (emphasis in original)*

There is still another compelling, and mutually exclusive, reason why the Ammann et al., and Melet patents cannot be combined and applied to reject claim 64 under 35 U.S.C. §103(a).

The courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. In the present case it is clear that the examiner's combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 64.

In particular, in the present case the means for inclining the receptacles of Melet are used for dual agitation so as to favor homogenization of the sample to be analyzed. Therefore, there is no motivation to combine Ammann et al., which has a device for agitating containers already (see Abstract etc.), with Melet whose subject matter of the invention relates to homogenization of the sample to be analyzed and is diametrically opposite to that of the present invention which relates to extraction of a liquid other than precipitate, in order to minimize

agitation of the container, but extract liquid other than a precipitate from the vessel and into the nozzle.

In contrast thereto, with the present invention, means for effecting relative vertical movement between the nozzle and vessel in order to insert the nozzle into the vessel, and a mechanism for inclining the nozzle and vessel with respect to a vertical axis to pass liquid, other than a precipitate, from the vessel and into the nozzle are mounted in an automatic separator/extractor. Namely, with the present invention, liquid other than a precipitate can efficiently and easily be extracted by use of the mechanism for inclining both said nozzle and vessel with respect to said vertical axis (and not inclining only the vessel with respect to the horizontal axis as Melet) so as to change the angle between the axis of the vessel and nozzle and the vertical axis in accordance with the amount or level of the remaining liquid in the vessel without influencing the precipitate as is shown on page 8, lines 20 to 23, of the original specification. Hence, the method of claim 64 not only is distinct from the Ammann et al. and Melet patents in that a mechanism for inclining the nozzle and vessel with respect to a vertical axis is mounted, but also has aforementioned remarkable advantages. Consequently, the present invention cannot be easily made on the basis of Ammann et al. and Melet and is not obvious to a person of ordinary skill in the art.

Therefore, for this mutually exclusive reason, the examiner's burden of factually supporting a *prima facie* case of obviousness clearly cannot be met with respect to claim 64, and the rejection under 35 U.S.C. §103(a) is not applicable.

Therefore, the rejection of independent claim 64 based on the combination of Ammann et al. and Melet under 35 USC §103 (a), is unwarranted and should be withdrawn.

In view of all of the above, it is clear that independent claims 32, 63 and 64 are in condition for allowance. Dependent claims 33-62 and 65-82 limit claims 32 and 64, respectively, in a patentable since are, therefore, also deemed to be in condition for allowance.

A formal notice of allowance of claims 32-83 is respectfully requested.

The examiner is invited to call the undersigned at the below-listed telephone number if, in the opinion of the examiner, such a telephone conference would expedite or aid the prosecution and examination of this application.

Respectfully submitted,

  
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Registration No. 22,732

Dated: \_\_\_\_\_

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This paper and fee are being deposited with the U.S. Postal Service Express Mail Post Office to Addressee service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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